MEMO ENDORSED

GIBSON DUNN

The Court will address this issue at the pre-motion conference scheduled for October 18, 2023, at 11:00 a.m. Defendant is directed to respond before that conference. SO ORDERED.

Edgardo Ramos, U.S.D.J.
Dated: October 17, 2023
New York, New York

Gibson, Dunn & Crutcher LLP
200 Park Avenue
New York, NY 10166-0193
Tel 212.351.4000
www.gibsondunn.com

October 16, 2023

VIA ECF

The Honorable Edgardo Ramos
United States District Court, Southern District of New York
500 Pearl Street
New York, NY 10007

Re: *Esperion Therapeutics, Inc. v. Daiichi Sankyo Europe GmbH*, 23-cv-02568 (S.D.N.Y.)

Dear Judge Ramos:

On behalf of Plaintiff Esperion Therapeutics, Inc. ("Esperion") we respectfully request permission to move for judgment on the pleadings under Federal Rule of Civil Procedure 12(c), based on the unambiguous terms of the parties' written contract.

Esperion makes lifesaving drugs that reduce major cardiovascular risks like heart attack and stroke. In 2019, Esperion and Defendant Daiichi Sankyo Europe GmbH ("DSE") signed a license agreement (the "Agreement") for DSE to distribute Esperion's products in Europe. The unambiguous terms of the Agreement require DSE to pay Esperion $300 million if certain conditions concerning regulatory approval are met, but DSE has repudiated its clear contractual obligation.

This dispute can be resolved on the pleadings because it involves a pure question of contractual interpretation and the material facts set forth in the pleadings are undisputed. Judgment on the pleadings is not just appropriate but urgently needed. The day the markets learned DSE had repudiated its obligation to pay Esperion, Esperion's stock price fell by 54%. It has fallen by more than another 50% since then. Esperion is now trading below $1 and faces the risk of de-listing from NASDAQ. Every day this dispute remains unresolved diminishes the odds of Esperion's continued existence and in turn imperils its life-saving drugs from reaching patients who desperately need them. For Esperion, judgment on the pleadings is not a matter of convenience. It may be a matter of survival.

"Judgment on the pleadings 'is appropriate where material facts are undisputed and where a judgment on the merits is possible merely by considering the contents of the pleadings.'" *Allstate Ins. Co. v. Vitality Physicians Grp. Prac. P.C.*, 537 F. Supp. 3d 533, 545 (S.D.N.Y. 2021) (citation omitted). Judgment on the pleadings is "particularly appropriate" in contract disputes where a "contract is unambiguous" and "the Court may determine the parties' rights and obligations as a matter of law." *Neopharm Ltd. v. Wyeth–Ayerst Int'l LLC*, 170 F. Supp. 3d 612, 615 (S.D.N.Y. 2016) (granting declaratory judgment on the pleadings to plaintiff on meaning of contract terms); *VoiceAge Corp. v. RealNetworks, Inc.*, 926 F. Supp. 2d 524, 529 (S.D.N.Y. 2013) (a contract "clear and unambiguous on its face" "must be enforced according to the plain meaning of its terms").

The disputed contractual language is unambiguous. Section 9.2 of the Agreement requires DSE to pay Esperion a "Regulatory Milestone Payment" if certain conditions are met. At the time the Agreement was signed, Esperion was conducting and funding a $500 million clinical study, known as the CLEAR Outcome Study, to measure how effectively its products reduced major

cardiovascular risks such as heart attack and stroke, among other risks. Once the study was complete, Esperion would apply for regulatory approval of a label. That label would include the indication for which the products should be used, along with the results of the study. The Agreement requires DSE to pay Esperion if Esperion obtains a label that includes an indication for "cardiovascular risk reduction," and also includes "a result of the CLEAR Outcome Study" "that correlates with" at least a 15% or 20% reduction in cardiovascular risk. *See* Dkt. 19-1 § 9.2.2.

The parties' pleadings do not dispute that the study contained multiple results showing reduced cardiovascular risk. DSE ***admitted*** in its Answer that the study included multiple "results" that demonstrated "a reduced risk of certain adverse cardiovascular events." Dkt. 33 ¶ 28, ¶ 54. The results include a 27% reduction in nonfatal heart attacks; 23% reduction in fatal and nonfatal heart attacks; 19% reduction in coronary revascularization; 15% reduction in fatal and nonfatal stroke. Dkt. 19 ¶ 54; Dkt. 33 ¶ 54. And the Agreement itself repeatedly states the study will have multiple results. *See* Dkt. 19-1 §§ 1.17 (citing the study's publicly available clinical protocol identifying numerous cardiovascular risk results to be measured); 3.2.2 ("labelling for the Licensed Product to include reference to the results of the CLEAR Outcome Study"); *id.* at Schedule 7.3 (press release to report that "cardiovascular risk reduction results are expected during 2022").

Recognizing that it would soon be on the hook for a $300 million payment to Esperion, DSE proffered a patently unreasonable and unsupportable interpretation of the Agreement for the purpose of not making the payment. Even though it admits that the study included multiple "results" that demonstrated "a reduced risk of certain adverse cardiovascular events," DSE now says that ***only one*** particular result—a composite result called MACE-4—could possibly trigger the milestone payment to Esperion. The question that will be presented by Esperion's motion, then, is straightforward: Does the Agreement provide that ***any one of several cardiovascular risk reduction results*** from the study could trigger DSE's payment obligation (as Esperion argues)—or is the payment obligation triggered by ***only one particular result*** (as DSE argues)?

This pure question of contract interpretation is not a close one and is readily susceptible to resolution on the pleadings. The plain language of the Agreement states that ***multiple*** cardiovascular risk reduction results—not just the MACE-4 result, as DSE claims—could trigger the payment obligation. Section 9.2 refers to "***a*** result of the CLEAR Outcome Study," using the indefinite article "a," rather than the definite article "the." *See CSX Transp., Inc. v. Island Rail Terminal, Inc.*, 879 F.3d 462, 471 (2d Cir. 2018) ("The use of the definite article 'the' indicates a singular [entity], whereas the indefinite article 'any' or 'a' denotes multiple [entities]"). By using "the indefinite article 'a,'" the Agreement confirms "the modified noun"—here, "result of the CLEAR Outcome Study"—"is but one of several of that kind." *Renz v. Grey Advert., Inc.*, 135 F.3d 217, 222 (2d Cir. 1997). In short, the Agreement requires DSE to pay if ***any*** of several results of the study shows cardiovascular risk reduction above 15% or 20% and is reflected in the label.

That reading is confirmed by neighboring language in Section 9.2 providing that the "milestone payment shall be payable only once." If DSE were correct that only one specific result of the study could trigger DSE's payment obligation, there would have been no need to specify that the milestone payment must be paid only once. The express limit of a single payment is a clear indicator that multiple results could trigger the payment obligation.

DSE's contrary interpretation—that only the "MACE-4" result could trigger its payment obligation—cannot be reconciled with the plain language of the Agreement. MACE-4 is a "composite" measure of four separate "major adverse cardiovascular events." Dkt. 33 ¶ 3. MACE-4 is not even ***mentioned*** anywhere in the 84-page Agreement, let alone designated as the only result that could trigger DSE's payment. "[T]he terms" DSE hopes to invent "are simply nowhere to be found in the relevant provisions of the contract." *Impax Lab'ys, Inc. v. Turing Pharms. AG*, 2017 WL 4357893, at *10 (S.D.N.Y. Sept. 29, 2017). The parties agreed DSE would pay Esperion if "***a*** result" of the study showed cardiovascular risk reduction above the specified level, and DSE admits, as it must, that the study included multiple "results" that demonstrated "a reduced risk of certain cardiovascular events." Dkt. 33 ¶ 28, ¶ 54. The parties did not say that only MACE-4 triggered the payment obligation. If the parties intended to tie DSE's payment obligation to MACE-4 results ***alone***, they knew how to say that and could have done so. They did not.

This is not a case where the parties' competing interpretations of a contract are both reasonable and the court needs to consult extrinsic evidence to determine the parties' intent. DSE's interpretation is not reasonable. This case can be resolved on the pleadings in Esperion's favor. "Where, as here, a contract is unambiguous, courts are required to give effect to the contract as written and may not consider extrinsic evidence to alter or interpret its meaning." *United States Tr. Co. of N.Y. v. Jenner*, 168 F.3d 630, 632 (2d Cir. 1999) (quotation marks omitted).

This case can and should be resolved now, on the pleadings. Esperion had hoped that the parties could proceed through discovery expeditiously, but that hope has been dashed. DSE knew that by repudiating its payment obligation, it would drive down Esperion's market value and put the company into a slow death spiral. Esperion comes to this Court seeking judgment now because it may not survive until the April 2024 trial.

The months of discovery ahead will demand significant resources from the parties and require the Court's regular intervention to resolve inevitable disputes, as the Court is already aware. *See* Dkts. 64, 68. The parties will introduce dueling witness testimony, documentary evidence, and experts. DSE knows that it will be very difficult if not impossible for Esperion to engage in full-blown discovery and pretrial proceedings given its financial straits—a dire situation that DSE has engineered. There is no need for the parties to spend millions of dollars, and the Court to devote months to supervising discovery, to resolve what is clear from the pleadings.

The path to final resolution of this dispute became apparent three weeks ago when European regulators preliminarily accepted language in proposed labels for Esperion's products. The labels include an indication for "cardiovascular risk reduction," just as Section 9.2 of the Agreement requires. The label also includes multiple results of the CLEAR Outcome Study showing cardiovascular risk reduction above 15% and 20%, also just as Section 9.2 requires. DSE has never denied those results. *See* Dkt. 19 ¶ 54; Dkt. 33 ¶ 54.

The European regulators' approval (once it becomes final) means that, if this Court grants Esperion a judgment affirming its interpretation of the Agreement, DSE's payment obligation will be triggered and this case will be over. And that means Esperion can make its life-saving drugs available to patients who urgently need them. DSE should not be able to destroy Esperion based on a patently unreasonable interpretation of the Agreement to avoid its payment obligations, especially when the stakes are so high. We thank the Court for its kind consideration of this matter.

Respectfully,

Orin Snyder

Cc: All counsel of record (via ECF)